

identical, they are not patentably distinct from each other; and that there is an overlap of the claimed genera. In response, Applicants will submit a Terminal Disclaimer upon the indication of allowable subject matter.

2. The Rejection Under 35 U.S.C. 112, First Paragraph

Claims 1-12 and 15 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is asserted that there is no evidence that any of the claimed compounds can stimulate release of growth hormone *in vitro* or *in vivo*. It is also suggested that in the event that only *in vitro* data are provided, the term "pharmaceutical" should be deleted from claim 15 since this term implies an assertion of therapeutic efficacy, which would not be in evidence even if the compounds do turn out to promote the release of growth hormone.

In response, Applicants submit herewith a copy of two Declarations submitted during the prosecution of related application serial no. 09/387,809. In the Declaration dated September 22, 2000, *in vivo* results were presented for nine compounds according to the invention (see paragraphs 6-8 of said Declaration), clearly demonstrating GH-releasing activity of the compounds. The compound of Example 15 was found to be a particularly potent growth hormone secretagogue *in vivo*.

Supplementary *in vivo* results for the compound of Example 15 were presented in the Declaration dated November 5, 2002, showing data for GH release in pigs as a function of time before and after administration of the compound of Example 15. Data for three concentrations of this compound are shown and demonstrate a dose-dependent GH-release stimulating effect.

Since the test results presented in the two Declarations are all *in vivo* results, Applicants respectfully submit that retention of the term "pharmaceutical" in claim 15 is justified. However, in order to advance prosecution, the term "pharmaceutical" has been removed from claim 15. Applicants reserve the right to pursue prosecution of cancelled subject matter in subsequent continuation and/or divisional applications.

In view of the above, Applicants assert that the rejection has been overcome. Therefore, Applicants respectfully request that the rejection be withdrawn.

3. The Rejection Under 35 U.S.C. 112, Second Paragraph

Claim 15 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. It is suggested that the phrase "effective amount" be deleted. In response and in order to advance prosecution, claim 15 has been amended to remove the phrase "effective amount". Therefore, the rejection has been overcome and should be withdrawn.

4. Conclusion

In view of the foregoing, it is believed that the present claims are in condition for allowance, and such a determination is earnestly solicited. The Examiner is invited to contact the undersigned at (914) 712-0093 if there are any remaining issues that need to be discussed

Respectfully submitted,

Date:

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AMENDED CLAIM 15-MARKED UP VERSION

15. (amended) A ~~pharmaceutical~~ composition comprising, as an active ingredient, a compound of claim 1, ~~in an amount effective to stimulate the release of growth hormone,~~ together with a carrier or diluent.